IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No	:	24126	Confirmation No.	6616
Applicant	:	Andersen et al.		
Serial No.	:	10/528,927	Art Unit:	1782
Filed	:	December 16, 2005	Examiner:	Saeeda Monee Latham
For	:	Biodegradable chewing gum comprising at least one high molecular weight biodegradable polymer		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is in support of Applicant's Notice of Appeal filed on November 29, 2010. Filed concurrently herewith is a Request for a one-month extension of time to respond to the outstanding Office Action, along with the appropriate fee therefor. Applicant believes that no further fee is due in connection with the filing of this Response. However, if any further fee is due please charge Deposit Account No. 19-4516.

APPEAL BRIEF

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I. Real Party in Interest

The real party in interest for the present application is Gumlink A/S, which is the assignee. Gumlink A/S is the assignee of record per an assignment recorded, on December 16, 2005, at Reel 017785, Frame 0379 by inventors Lone Andersen and Helle Wittorff.

II. Related Appeals and Interferences

To the best of the Appellant's knowledge, there are no appeals or interferences which are directly related to the present appeal.

III. Status of Claims

Claims 1-58 were originally filed in the present application and were amended a number of times in response to objections as set forth in paper no. 20080220, paper no. 20080829, paper no. 20090106, paper no. 20090505, paper no. 20091210 and paper no. 20100727.

Claims 3-5, 7, 10-13, 27, 32, 51, 54-55, and 57-58 have been cancelled.

Present Claims 1-2, 6, 8-9, 14-26, 28-31, 33-50, 52-53, and 56 remain pending, are the subject of the present appeal and are set forth in the Appendix (section VIII) to this Appeal Brief.

IV. Status of Amendments

There have been no amendments to the claims or specification filed after the final Office Action of July 27, 2010.

V. Summary of the Claimed Subject Matter

The present technology is directed to a chewing gum comprising at least one biodegradable polymer.

It is an object of the invention to provide a biodegradable chewing gum capable of incorporating at least certain important chewing gum ingredients. Furthermore it is an object of the invention to formulate a biodegradable chewing gum with properties with respect to storage stability, texture and release of, e.g., flavor comparable to similar properties of conventional chewing gum. In this context, it is important to note that biodegradable polymers for use in chewing gum by nature may differ considerably from conventional chewing gum polymers with respect to both physical and chemical properties.

According to the present invention, these objects have been achieved according to the provisions set forth in present independent Claim 1, which is directed to a chewing gum comprising at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn); and at least one softener in an amount of less than 12% by weight of the chewing gum. Furthermore the chewing gum is free of non-biodegradable polymers. (Application, page 2, lines 5-7, page 3, lines 29-31, page 6, lines 16-18, page 7, lines 22-23)

In another respect, these objects have been achieved according to the provisions set forth in present independent Claim 50, which is directed to a method of creating a chewing gum with

increased robustness comprising the steps of: (i) providing at least one biodegradable polymer; (ii) adjusting the molecular weight of the at least one biodegradable polymer to be within the range of 105000g/mol (Mn) to 350000 g/mol (Mn); and (iii) mixing the at least one biodegradable polymer with at least one softener in an amount of less than 12% by weight of the chewing gum. (Application, page 2, lines 5-7, page 3, lines 29-31, page 6, lines 16-18)

According to the invention, it has been realized that chewing gums made on the basis of biodegradable polymers are somewhat vulnerable to different conventional chewing gum additives or components. Most critically, it has been realized that softeners, which are highly needed when obtaining the desired chewing gum texture, tend to dissolve the chewing gums even when applied in small amounts. (Application, page 2, lines 9-13)

According to the invention, it has moreover been realized that this problem may be effectively dealt with by increasing the molecular weight of at least one of the biodegradable polymers in the chewing gum when compared to conventional chewing gum polymers and thereby increasing the robustness of the chewing gum with respect to softeners, emulsifiers and, e.g., flavor. (Application, page 2, lines 15-19)

According to the invention, it has moreover been realized that an increasing of the molecular weight of at least one of the biodegradable polymers and thereby an increasing of the rheological stiffness (G') may in fact be more than compensated by addition of softeners. (Application, page 2, lines 21-24)

In other words, according to the invention an improved texture of a biodegradable polymer containing chewing gum may in fact surprisingly be obtained by an initial worsening of the rheological properties of the biodegradable polymer and finally be more than compensated by the addition of suitable softeners. (Application, page 2, lines 26-29)

Due to the hydrophilic nature of biodedegradable polymers, the polymers tends to swell in water, e.g., from mouth induced saliva. Thereby, the intermolecular forces between the neighboring molecular chains will decrease and the chewing gum structure will weaken. (Application, page 2, line 31 to page 3, line 2)

According to the invention, a higher resistance to the decreasing of intermolecular forces has been obtained partly due to the fact that the resulting intermolecular forces are increased between the polymer chain and moreover due to the fact that the increasing of the size of the molecular chains results in increased entanglement between the polymer chains of neighboring polymers. (Application, page 3, lines 4-9)

According to the invention, it has moreover been realized that an improved long-term release of chewing gum ingredients may be obtained, with increased molecular weight of the applied biodegradable polymer. (Application, page 3, lines 10-12)

VI. Grounds of Rejection to be Reviewed on Appeal

There are four grounds of rejection to be reviewed on appeal. It should be noted that the rejections of claims 1, 2, 6, 8, 9, 14-26, 28-31, 33-50, 52, 53 and 56 in the form of obviousness-type double patenting rejections from the Final Office Action are acknowledged and these rejections are **not** being appealed, but will be addressed after the appeal on the merits is decided should such be necessary. The grounds of rejection to be reviewed on appeal are as follows:

A. The rejection of claims 1, 2, 6, 8, 9, 14-18, 20-26, 28-31, 33-39, 49, 50, 52, 53, and 56 under 35 U.S.C. §103(a) as obvious over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378).

B. The rejection of claims 40-48 under 35 U.S.C. §103(a) as obvious over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378), in further view of Zyck et al. (US2001/0021373).

C. The rejection of claims 1, 2, 6, 8, 9, 14-18, 20-26, 28-31, 33-39, 49, 50, 52, 53, and 56 under 35 U.S.C. §103(a) as obvious over Li et al. (WO00/19837).

D. The rejection of claims 40-48 under 35 U.S.C. §103(a) as obvious over Li et al. (WO00/19837) in view of Zyck et al. (US2001/0021373).

VII. Argument

An invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[1] For a claim to be rejected as obvious, the Office is required to determine the scope and content of the prior art, ascertain the differences between the claimed invention and the prior art, and resolve the level of ordinary skill in the art.[2] This analysis must be set forth explicitly.[3] When considering the prior art, the office is required to consider the prior art as a whole, and may not disregard portions of the art which show that an invention is not obvious.[4] Additionally, it is important to guard against the use of hindsight when evaluating whether a claim is obvious.[5] As a guard against hindsight, courts have identified certain scenarios in which it is improper to reject a claim as obvious. For example, a claim cannot properly be rejected as obvious when the principle of operation of the prior art would need to be modified to obtain the claimed invention.[6] Similarly, if a prior art reference teaches away from a claimed invention, then the claimed invention is not obvious over that prior art.[7] Given these standards, the Office's rejections under 35 U.S.C. § 103(a) cannot be sustained and must be reversed for the reasons set forth below.

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[1] 35 U.S.C. § 103(a).
[2] *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007); MPEP § 2141, citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966).
[3] *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).
[4] *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).
[5] *E.g., KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.").
[6] *In re Ratti*, 270 F.2d 810 (CCPA 1959) (cited in MPEP 2143.01 for the proposition that "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").
[7] *See* MPEP § 2145 citing *In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983).

A summary of the rejections from the Examiner follows:

According to the rejection as set forth in paragraph no. 6, paper no. 20100727, the Examiner acknowledges that neither Grijpma nor Ohara explicitly teaches a number average molecular weight or polydispersity. Further she asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures to yield the desired number average molecular weight and polydispersity.

According to the rejection as set forth in paragraph no. 21, paper no. 20100727, the Examiner acknowledges that Li does not teach the biodegradable polymer of at least 105000 g/mol or higher (Mn) or polydispersity. Further she asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures to yield the poly (D, L-lactic acid) of Li with the desired molecular weight and polydispersity using the ranges taught.

In the "Response to Arguments" section, the Examiner in paragraph no. 36, paper no. 20100727, sets forth the following in response to the argumentation from the Appellant that Ohara is not relevant to the art of chewing gum:

> 36. In response to applicant's argument, both Grijpma and Ohara teach biodegradable polymers made of lactides using copolymerized lactones (see Grijpma column 1, lines

> 57-62, Ohara column 3, lines 8-12). In this case, Ohara is used as evidence of polymers made of lactides using copolymerized lactones that have specific properties not taught by Grijpma. Further, Ohara teaches the method for producing a polylactic acid that is biologically safe, having a high molecular weight of 200,000 to 500,000, and is freed from coloration and containing substantially no decomposition products (Column 1, lines 14; Column 2, lines 22-24). The presences of lactides and decomposition products cause undesirable adherence to nozzles during molding and deterioration of polymer formability and thermal stability (Column 1, lines 54-61). Ohara further teaches the polylactic acid can be further progressed and unreacted lactide can be reacted further, the reaction can be terminated to yield an average high molecular weight polymer (column 2, lines 5-7, examples 1-12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the teachings of Ohara to make the high average molecular weight polylactic acid that contains substantially no decomposition products to produce Grijpma's biodegradable gum using a good quality formable polymer.

In the "Response to Arguments" section, the Examiner in paragraph no. 38, paper no. 20100727, sets forth the following in response to the argumentation from the Appellant that Li does not define the molecular weights well:

> 38. In response to applicant's argument, Li teaches several embodiments wherein the poly (D/L-lactic acid) has a molecular weight range of approximately 2000 to about 2000000 g/mol and 10000 to about 500,000 g/mol (Page 2, lines 27, 30). Although Li does not teach Mn, the fact that the range is taught, would permit one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures and selected the polymer Mn above 105,000 g/mol and still be within the range taught by Li.

The problem arising when combining chewing gum ingredients with biodegradable gum base polymers is not addressed in either Grijpma et al. or Li et al.

At the time the invention was made, the use of biodegradable polymers was still in its infancy and the real problems encountered when using these polymers in gum base compositions were not identified or described.

As such, problems not even encountered or mentioned in the prior art, but identified and solved according to the present invention, are asserted to be a pointer to non-obviousness, see, e.g., *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008).

In this case, some of the problems solved by the present invention and summarized under section V. Summary of the Claimed Subject Matter, are not in any way mentioned or dealt with in the prior art. For example, when Grijpma et al. relate their chewing gum to conventional chewing gum, this is based on the low molecular weight biodegradable polymers used, and not at all on any compositional features. The teachings of Grijpma et al. suggest that the use of the low molecular weight biodegradable polymers provides an even simpler chewing gum composition than conventional chewing gum in that the biodegradable polymer constitutes the whole gum base.

According to the present invention, a better approach is to use high molecular weight biodegradable polymers and to adjust the texture with sufficient softener and at the same time achieve a more robust composition, even though the resulting chewing gum is free of non-biodegradable polymers.

A. Claims 1, 2, 6, 8, 9, 14-18, 20-26, 28-31, 33-39, 49, 50, 52, 53, and 56 are not properly rejected under 35 U.S.C. 103(a) over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378).

The Examiner has improperly rejected claims 1, 2, 6, 8, 9, 14-18, 20-26, 28-31, 33-39, 49, 50, 52, 53, and 56 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378).

Grijpma et al. is directed to gum bases comprising a degradable copolymer (examples 1-4) and chewing gums comprising such gum bases. Grijpma et al. is focused on the use as such of the degradable copolymer in a gum base, and Grijpma et al. is consequently completely silent with respect to whether some molecular weights (Mn) of the biodegradable polymers used will be better than others.

Ohara et al. discloses a method for producing polylactic acid (PLA) having a molecular weight of 200,000 – 500,000 (Col. 2, Lines 19-24). The polymers of Ohara et al. are intended for technical uses such as medical purposes, including surgical sutures, sustained release capsules in drug delivery systems, and reinforcing materials for bone fractures (Col. 1, Lines 14-24). The polymers of Ohara et al. have glass transition temperatures between 57.3 °C (Ex. 6) and 64 °C (Ex. 8).

Appellant respectfully submits that Ohara et al. is not at all relevant with respect to the art of chewing gum and would, as such, not be consulted by the person skilled in the chewing gum art. If, although contested by the Appellant, the skilled person in the chewing gum art, at the time

the invention was made, would have looked into the teachings of Ohara et al., he/she would clearly refrain from considering the taught polymers for use in chewing gum. The reason for this is that the polymers taught in Ohara are all crystalline technical plastics made from L-lactide; e.g., all examples refers to using "L-lactide (manufactured by Purac)". The skilled person would know that polymers made from such monomers are too crystalline as a chewing gum component, which, e.g., is reflected by Li et al. (col. 6, lines 17-19), in which it is stated:

> Since the common form, PLLA, is highly crystalline and has a glass transition temperature (Tg) around 58 °C, it is rigid at room temperature and, not suitable as a chewing gum masticatory ingredient.

In paragraph no. 36, paper no. 20100727 the Examiner states:

> It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the teachings of Ohara to make the high average molecular weight polylactic acid that contains substantially no decomposition products to produce Grijpma's biodegradable gum using a good quality formable polymer.

However, on the basis of the knowledge of the skilled person, as noted by Li above, indeed there would be no motivation to use the teaching from Ohara with Grijpma; moreover Ohara seems almost irrelevant for even being considered as a prior art document in relation to the present invention.

In paragraph no. 6, paper no. 20100727 the Examiner acknowledges that Grijpma and Ohara are both silent as to a number average molecular weight and polydispersity. However, the Examiner states that "it would have been obvious to one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures to yield the desired number average molecular

weight and polydispersity." This statement is considered as trying to argue obviousness on the basis of Grijpma without the disclosure of Ohara.

The Appellant disagrees with this statement from the Examiner and refers to the passages stated above in the beginning of section VII citing some case law, in particular *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008).

Further, from the summary of the claimed subject matter (section V), a number of benefits with the present invention can be seen. Here can, e.g., be seen, according to the present invention, that the use of softeners is problematic when utilizing biodegradable polymers in chewing gum, as described in the present application on page 2, lines 9-13. To obtain a biodegradable chewing gum with an adequate texture, the Appellant has found that a relatively high molecular weight biodegradable polymer can be combined with softeners, the relatively high molecular weight of the polymer allowing the use of effective amounts of softener, and the softener more than compensating for the intrinsically poor rheological properties of the high molecular weight biodegradable polymer. At the same time, due to the at least one biodegradable polymer, the use of softeners is somewhat restricted, which is specified in both Claims 1 and 50.

Furthermore, to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR*

International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1389 (2007). It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.*

Present claim 1 covers a chewing gum with three restrictions:

- at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn);

- at least one softener in an amount of less than 12% by weight of the chewing gum; and

- wherein the chewing gum is free of non-biodegradable polymers.

As noted by the Examiner and previously stated, Grijpma et al. is silent as to the number average molecular weight used in their inventions. Furthermore, and consequently, no indication can be found on whether the use of certain molecular weights may have an effect not otherwise obtained.

In paragraph no. 4, paper no. 20100727, the Examiner states that:

> Grijpma does not explicitly teach less than 12% softeners. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected 0.5 to less than 12% because of the overlapping range of Grijpma.

In other words, the Examiner recognizes both that Grijpma is silent to number average molecular weight used in their invention and furthermore Grijpma has no explicit teaching on softener amount less than 12 %. Consequently, starting from Grijpma et al., it would in no way be obvious whether anything could be achieved by employing at least one biodegradable

polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn). Essentially, until the Appellant made the contribution as claimed herein, a skilled person starting from Grijpma et al. would not have recognized any reason to make the modifications to their formulations, which are necessary to arrive at the claimed invention.

Furthermore, starting from Grijpma et al., it would in no way be obvious whether the amount of softeners would be important. No indication of any problems related to the combination of biodegradable polymers with softeners are disclosed in Grijpma et al. Hereby the skilled person would not be able to reach the distinct unexpected advantages and effects achieved by tuning the amount of softener to the biodegradable polymer as explained above.

Finally in paragraphs no. 3, paper no. 20100727, the examiner states that "in the absence of the teaching that the chewing gum is free of non-biodegradable polymers, it is understood that the claim limitation is met". However, again this would be a choice that the skilled person would have to make.

A number of advantages related to the use of the comparatively high molecular weight of the polymers included in the chewing gum of the present invention are mentioned in the description of the present invention, e.g., on page 2, line 9 to page 3, line 8 cited above under "Summary of the Claimed Subject Matter".

The fact that these can be found according to the present invention by the employment of at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn) would not be found nor even indicated in Grijpma et al. and furthermore the skilled person would not find any reason to restrict the amount of softeners as specified in both present Claims 1 and 50.

It is therefore respectfully submitted that "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" is missing.

Ohara has apparently been introduced by the Examiner to show that degradable polymers can be made with high molecular weights. However, as mentioned above, the polymers of Ohara are well-known by the skilled person as not suitable for chewing gum. Consequently, Ohara is either teaching away from the present invention or is irrelevant.

Therefore the skilled person would not be led towards a chewing gum according to the provisions of current Claim 1, and a method according to current Claim 50. Hence independent Claims 1 and 50 and all dependent claims are non-obvious over Grijpma et al. in view of Ohara et al. and this rejection under 35 U.S.C. 103(a) should be withdrawn.

B. Claims 40-48 are not properly rejected under 35 U.S.C. §103(a) over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378), in further view of Zyck et al. (US2001/0021373).

The Examiner has improperly rejected claims 40-48 under 35 U.S.C. §103(a) as being unpatentable over Grijpma et al. (US 5,672,367) in view of Ohara et al. (US 5,508,378), in further view of Zyck et al. (US2001/0021373).

Rejected claims 40-48 are all ultimately dependent on Claim 1; consequently, all arguments set forth in relation to Claim 1 above over Grijpma et al. in view of Ohara et al. apply as well. Furthermore, in paragraph no. 18, paper no. 20100727, the Examiner states that:

> *[I]t would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized conventional panning techniques to coat gum taught by Zyck and further processed the gum pellets of Grijma to produce a coated chewing gum.*

Grijpma et al. discloses biodegradable gums; however, Grijpma et al. does neither teach nor suggest *coating* these degradable gums using a water-based (i.e., aqueous) process. Probably this is deliberate by Grijpma et al. The fact is that a skilled person in the art of degradable chewing gum would expect that a biodegradable gum base (polymer) would readily decompose (hydrolytically) upon exposure to an aqueous coating process. In this regard it is noted that the coating process described in Zyck et al. comprises 20-70% of a solvent such as water (paragraph [0062]), and the skilled person would expect such a coating process to readily decompose the biodegradable gum base (polymer) described in Grijpma et al.

However, the Appellant has surprisingly found that this is not so and the Appellant can produce a coated, environmentally degradable chewing gum using a water-based process.

Accordingly, the rejections under 35 U.S.C. 103(a), based upon Grijpma et al. in view of Ohara et al., in further view of Zyck et al. have been overcome and should be withdrawn.

C. Claims 1, 2, 6, 8, 9, 14-26, 28-31, 33, 36-39, 49, 50, 52, 53, and 56 are not properly rejected under 35 U.S.C. §103(a) over Li et al. (WO00/19837).

The Examiner has improperly rejected claims 1, 2, 6, 8, 9, 14-26, 28-31, 33, 36-39, 49, 50, 52, 53, and 56 under 35 U.S.C. §103(a) as being unpatentable over Li et al. (WO00/19837).

In the "Response to Arguments" section, the Examiner in paragraph no. 38, paper no. 20100727, sets forth the following in response to the argumentation from the Appellant that Li does not well define the molecular weights (it is noted that the Examiner states almost the same in paragraph no. 21, paper no. 20100727):

> *38. In response to applicant's argument, Li teaches several embodiments wherein the poly (D/L-lactic acid) has a molecular weight range of approximately 2000 to about 2000000 g/mol and 10000 to about 500,000 g/mol (Page 2, lines 27, 30). Although Li does not teach Mn, the fact that the range is taught, would permit one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation and optimization procedures and selected the polymer Mn above 105,000 g/mol and still be within the range taught by Li.*

Appellant wishes to emphasize that the teachings in Li et al. relate to a single commercial polymer mentioned in Li et al., Example 1. The viscosity molecular weight (Mv) of the polymer in Li et al. is 42,200 g/mol, which implies that the number average molecular weight is even lower and therefore well outside the range of amended Claim 1. (For a polydisperse polymer Mw

> Mv > Mn, see e.g. page 22 in *Principles of polymerization* by George Odian, 4th Edition, 2004, John Wiley & Sons, Inc.).

Moreover, the Appellant is puzzled as to how the following quoted text:

In an embodiment, the poly(D,L-lactic acid) has a molecular weight of from approximately 2000 to about 2,000,000 g/mol.

In an embodiment, the poly(D,L-lactic acid) has a molecular weight of from approximately 10,000 to about 500,000 g/mol.

can justify the statement "*Li teaches several embodiments...*" as stated by the Examiner.

The Appellant holds the view that the ranges disclosed in Li et al. are not well defined since the molecular weights are not specified with regard to type (Mn, Mw, Mv or others). However, even if ignoring this insufficient disclosure of Li, still the ranges set forth in Li et al. remain nonspecific and unclear and do not contain unambiguous information about what is preferable or beneficial. As such it is difficult to see how the arbitrary upper limits of Mv in Li et al. "permit one having ordinary skill in the art at the time of the invention to have known how to modify conditions during the course of routine experimentation...."

There is no reason to believe that a skilled person would find motivation to arrive exactly in the Mn range in present Claim 1 of 105,000 g/mol to 350,000 g/mol. In other words, it would not have been obvious to the skilled person that certain benefits may be obtained by choosing biodegradable polymers with molecular weights in the range specified in Claim 1. To the contrary, Li et al. teaches only one specific example far outside the presently claimed range and

does in no way link molecular weight of the polymer to any positive property related to the chewing gum itself. Surprisingly a number of benefits have been found by Appellant, namely those cited from the application in section V. above, "Summary of the Claimed Subject Matter".

From this summary can furthermore be seen, according to the present invention, that the use of softeners is problematic when utilizing biodegradable polymers in chewing gum, as described in the present application on page 2, lines 9-13. To obtain a biodegradable chewing gum with an adequate texture, the Appellant has found that a relatively high molecular weight biodegradable polymer can be combined with softeners, the relatively high molecular weight of the polymer allowing the use of effective amounts of softener, and the softener more than compensating for the intrinsically poor rheological properties of the high molecular weight biodegradable polymer. At the same time, due to the at least one biodegradable polymer, the use of softeners is somewhat restricted, which is specified in both Claims 1 and 50.

Furthermore, to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co. v. Teleflex Inc.,* 82 USPQ2d 1385, 1389 (2007). It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.*

Present Claim 1 covers a chewing gum with three restrictions:

- at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn);

- at least one softener in an amount of less than 12% by weight of the chewing gum; and

- wherein the chewing gum is free of non-biodegradable polymers.

As noted by the Examiner and previously stated, Li et al. is silent as to the number average molecular weight used in their inventions. Furthermore, and consequently, no indication can be found on whether the use of certain molecular weights may have an effect not otherwise obtained.

In paragraph no. 22, paper no. 20100727, the Examiner states that:

> Li does not explicitly teach less than 12% softeners. It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have selected 0.5 to less than 12% because of the overlapping range of Li.

In other words, the Examiner recognizes both that Li is silent to number average molecular weight used in their invention and furthermore Li has no explicit teaching of a softener amount less than 12 %. Consequently, starting from Li et al., it would in no way be obvious whether anything could be achieved by employing at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn). Essentially, until the Appellant made the contribution as claimed herein, a skilled person starting from Li et al. would not have recognized any reason to make the modifications to their formulations, which are necessary to arrive at the claimed invention.

Furthermore, starting from Li et al., it would in no way be obvious whether the amount of softeners would be important. No indication of any problems related to the combination of biodegradable polymers with softeners are disclosed in Li et al. Hereby the skilled person would not be able to reach the distinct unexpected advantages and effects achieved by tuning the amount of softener to the biodegradable polymer as explained above.

Finally in paragraphs no. 22, paper no. 20100727, the Examiner states that "in the absence of the teaching that the chewing gum is free of non-biodegradable polymers, it is understood that the claim limitation is met". However, again this would be a choice that the skilled person would have to make.

A number of advantages related to the use of the comparatively high molecular weight of the polymers included in the chewing gum of the present invention are mentioned in the description of the present invention, e.g., on page 2, line 9 to page 3, line 8 cited above under "Summary of the Claimed Subject Matter".

The fact that these can be found according to the present invention by the employment of at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn) would not be found nor even indicated in Li et al. and furthermore the skilled person would not find any reason to restrict the amount of softeners as specified in both present Claims 1 and 50.

It is therefore respectfully submitted that "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" is missing.

Therefore the skilled person could not by looking in Li et al. arrive at the present invention as no teachings at all in Li et al. point in the direction of present Claim 1 or present Claim 50. To the contrary, the teachings of Li et al. favor the use of comparatively low molecular weight biodegradable polymers as evidenced by the examples in Li et al.

Consequently, independent Claims 1 and 50 and all dependent claims are non-obvious over Li et al. and this rejection under 35 U.S.C. 103(a) should be withdrawn.

Accordingly, the rejections under 35 U.S.C. 103(a), based upon Li et al. have been overcome and should be withdrawn.

D. Claims 40-48 are not properly rejected under 35 U.S.C. §103(a) over Li et al. (WO00/19837) in view of Zyck et al. (US2001/0021373).

The Examiner has improperly rejected claims 40-48 under 35 U.S.C. §103(a) as being unpatentable over Li et al. (WO00/19837) in view of Zyck et al. (US2001/0021373).

Rejected claims 40-48 are all ultimately dependent on Claim 1; consequently, all arguments set forth in relation to Claim 1 above over Li et al. apply as well. Furthermore, in paragraph no. 34, paper no. 20100727, the Examiner states that:

> [I]t would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized conventional panning techniques to coat gum as taught by Zyck and the gum pellets/sticks of Li to produce a coated chewing gum.

Li et al. discloses biodegradable gums; however, Li et al. does neither teach nor suggest *coating* these degradable gums using a water-based (i.e., aqueous) process. Probably this is deliberate by Li et al. The fact is that a skilled person in the art of degradable chewing gum would expect that a biodegradable gum base (polymer) would readily decompose (hydrolytically) upon exposure to an aqueous coating process. In this regard it is noted that the coating process described in Zyck et al. comprises 20-70% of a solvent such as water (paragraph [0062]), and the skilled person would expect such a coating process to readily decompose the biodegradable gum base (polymer) described in Li et al.

However, the Appellant has surprisingly found that this is not so and the Appellant can produce a coated, environmentally degradable chewing gum using a water-based process.

Accordingly, the rejections under 35 U.S.C. 103(a), based upon Li et al. in view of Zyck et al. have been overcome and should be withdrawn.

CONCLUSION

In summary and in light of the foregoing, Appellants respectfully request that the pending rejections be reversed, and that the pending claims be allowed in their present form.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. Chewing gum comprising:

at least one biodegradable polymer having a molecular weight within the range of 105000 g/mol (Mn) to 350000 g/mol (Mn); and

at least one softener in an amount of less than 12% by weight of the chewing gum;

wherein the chewing gum is free of non-biodegradable polymers.

2. Chewing gum according to claim 1, wherein the molecular weight of said at least one biodegradable polymer is within the range of 150000 g/mol (Mn) to 350000 g/mol (Mn).

3. - 5. (Canceled)

6. Chewing gum according to claim 1, wherein the molecular weight of said at least one biodegradable polymer is within the range of 105000 g/mol (Mn) to 250000 g/mol (Mn).

7. (Canceled)

8. Chewing gum according to claim 1, wherein the polydispersity of said at least one biodegradable polymer is within the range of 1 to 5.

9. Chewing gum according to claim 1, wherein the polydispersity of said at least one biodegradable polymer is within the range of 1 to 2.5.

10. - 13. (Canceled)

14. Chewing gum according to claim 1, wherein said chewing gum comprises flavoring agents.

15. Chewing gum according to claim 14, wherein said flavoring agents comprises natural and synthetic flavorings in the form of natural vegetable components, essential oils, essences, extracts, powders, including acids or other substances capable of affecting the taste profile.

16. Chewing gum according to claim 14, wherein said chewing gum comprises flavoring agents in an amount of 0.01 to about 30 wt%, said percentage being based on the total weight of the chewing gum.

17. Chewing gum according to claim 14, wherein said chewing gum comprises flavoring agents in an amount of 0.2 to about 4 wt%, said percentage being based on the total weight of the chewing gum.

18. Chewing gum according to claim 14, wherein said flavoring agent comprises water soluble ingredients.

19. Chewing gum according to claim 18, wherein said flavoring agent comprises acids.

20. Chewing gum according to claim 14, wherein said flavor comprises water insoluble ingredients.

21. Chewing gum according to claim 1, wherein said chewing gum comprises sweeteners.

22. Chewing gum according to claim 21, wherein said sweetener comprises bulk sweeteners.

23. Chewing gum according to claim 22, wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to about 95% by weight of the chewing gum.

24. Chewing gum according to claim 21, wherein said sweetener comprises high intensity sweeteners.

25. Chewing gum according to claim 24, wherein the high intensity sweeteners comprise sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, stevioside, alone or in combination

26. Chewing gum according to claim 24, wherein the chewing gum comprises high intensity sweeteners in an amount of less than 1% by weight of the chewing gum.

27. (Canceled)

28. Chewing gum according to claim 1, wherein the at least one softener comprises tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids, stearic acid, palmitic acid, oleic acid, linoleic acid or mixtures thereof.

29. Chewing gum according to claim 27, wherein the chewing gum comprises softeners in the amount of less than 18% by weight of the chewing gum.

30. Chewing gum according to claim 1, wherein said chewing gum comprises active ingredients.

31. Chewing gum according to claim 30, wherein said active ingredients are selected from the group consisting of: Acetaminophen, Acetylsalicylic acid, Buprenorphine, Bromhexin, Celcoxib, Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Rofecoxib, Tenoxicam, Tramadol, Valdecoxib, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron, Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, Ieco-Ceterizin,

Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium, Haloperidol, Allopurinol, Colchinine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorfin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetrizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine, Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphtalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetonid, Melatonine, Phenobarbitol, Caffeine, Benzodiazepines, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin, Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and/or Ratinidine or derivates and mixtures thereof.

32. (Canceled)

33. Chewing gum according to claim 1, wherein the at least one biodegradable polymer obtained by the polymerization of one or more cyclic esters by ring-opening and where at least one of the cyclic esters are selected from the groups consisting of glycolides, lactides, lactones, cyclic carbonates and mixtures thereof.

34. Chewing gum according to claim 33, wherein lactone monomers are chosen from the group consisting of ε-caprolactone, δ-valerolactone, γ-butyrolactone, β-propiolactone and mixtures thereof; and wherein the lactone monomers are optionally substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom.

35. Chewing gum according to claim 33, wherein the carbonate monomer is selected from the group consisting of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, 1, 3-dioxepan-2-one and mixtures thereof.

36. Chewing gum according to claim 33, wherein cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers are selected from the group consisting of poly (L-lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide) ; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ; poly (L

lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ; poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly (glycolide-co-epsilon-caprolactone); and mixtures thereof.

37. Chewing gum according to claim 1, wherein the chewing gum comprises filler.

38. Chewing gum according to claim 37, wherein the chewing gum comprises filler in an amount of less than 50% by weight of the chewing gum.

39. Chewing gum according to claim 1, wherein the chewing gum comprises at least one coloring agent.

40. Chewing gum according to claim 1, where the chewing gum is coated with an outer coating.

41. Chewing gum according to claim 40, wherein the outer coating is a hard coating.

42. Chewing gum according to claim 41, wherein the hard coating is a coating selected from the group consisting of a sugar coating, a sugarless coating, and a combination thereof.

43. Chewing gum according to claim 41, wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.

44. Chewing gum according to claim 40, wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

45. Chewing gum according to claim 44, wherein the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

46. Chewing gum according to claim 40, wherein the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a colouring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar, an acid and an agent capable of accelerating the after-chewing degradation of the degradable polymer.

47. Chewing gum according to claim 40, wherein the outer coating is a soft coating.

48. Chewing gum according to claim 47, wherein the soft coating comprises a sugar free coating agent.

49. Chewing gum according to claim 1, wherein said chewing gum comprises at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum, at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and at least one chewing gum ingredient chosen from the group consisting of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

50. Method of creating a chewing gum with increased robustness comprising the steps of: providing at least one biodegradable polymer adjusting the molecular weight of the at least one biodegradable polymer to be within the range of 105000g/mol (Mn) to 350000 g/mol (Mn); and mixing the at least one biodegradable polymer with at least one softener in an amount of less than 12% by weight of the chewing gum.

51. (Canceled)

52. Method of creating a chewing gum with increased robustness according to claim 50, wherein the molecular weight of said biodegradable polymer is adjusted to be within the range of 150000 g/mol (Mn) to 350000g/mol (Mn).

53. Method of creating a chewing gum with increased robustness according to claim 50, whereby the molecular weight of said biodegradable polymer is adjusted to be within the range of 250000 g/mol (Mn) to 350000 g/mol (Mn).

54 - 55. (Canceled)

56. Method of creating a chewing gum with increased robustness to claim 50, wherein the molecular weight of said at least one biodegradable polymer is adjusted within the range of 105000 g/mol (Mn) to 250000 g/mol (Mn).

57. - 58. (Canceled)

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.